

**REMARKS**

The foregoing amendments and following remarks accompany the Request for Continued Examination (RCE) filed herewith. Claims 3 and 4 have been amended. Support for the amendments can be found throughout the specification as filed. For example, support can be found at page 2, lines 12-13, and in Example XIII. New claim 32 has been added. Support for new claim 32 can be found, for example, at page 10, lines 13-14 and Example XIV. No new matter is believed to have been introduced.

**I. OBVIOUSNESS TYPE DOUBLE PATENTING**

Claims 3-8 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 3-5, and 6-9 of U.S. Patent No. 5,696,080 (the '080 patent). Applicant respectfully traverses this rejection.

Claims 3 and 4 (upon which claims 5-8 depend) have been amended to delete SEQ ID NO:1. The Examiner has incorrectly concluded that SEQ ID NO:2 is taught by the '080 patent. Applicant submits that SEQ ID NO:2 (comprising a D-Ala) is not taught or suggested in the '080 patent since this is a modified sequence as taught at page 11, lines 19-22 of the specification. Accordingly, the obviousness-type double patenting rejection may be withdrawn.

**II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 4-8 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the

claimed invention. Applicant respectfully traverses this rejection.

The Office Action alleges that there is no proper antecedent basis nor conception in the context with that described within the specification at the time of filing the application for the recitations of "treating neuropathic pain" or "in an effective amount that is greater than 20 µg/kg and less than 100 µg/kg of body weight".

Applicant has amended claim 4 upon which claims 5-8 depend. Applicant has amended the claim to recite "a neuropathic pain alleviating effective amount. . .". Support for the phrase can be found throughout the specification as filed (see, e.g., page 2, lines 12-13; and page 24, lines 1-10, Example XIII). Furthermore, the Examiner is respectfully directed to page 24, lines 1-10, which provides support for the dosage reflected in original claim 4. Applicant, however, has amended claim 4 to remove recitation of the dosages. Applicant believes that the foregoing remarks and amendments address the Examiner's rejection. Accordingly, Applicant respectfully requests withdrawal of the §112, first paragraph rejection.

### **III. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 4-8 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards and the invention.

The Office Action alleges that the recitation of "in an effective amount that is greater than 20 µg/kg and less than 100 µg/kg of body weight" is ambiguous as it cannot be determined before-the-fact for this product claims. Applicant has amended claim 4 upon which claims 5-8 depend to better set forth Applicant's claimed invention. Accordingly, Applicant

respectfully requests withdrawal of the \$112, second paragraph rejection. To the extent that this rejection is directed to the "effective amount" limitation, the Examiner's attention is drawn to In re Caldwell 138 UPQ 243, which sanctions limitation of this type.

**IV. REJECTION UNDER 35 U.S.C. §102(e)**

Claims 3-8 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by O'Brien et al. (U.S. Patent No. 5,696,080).

Claims 3 and 4 have been amended to remove recitation of SEQ ID NO:1. Applicant respectfully submits that the Examiner has incorrectly concluded that SEQ ID NO:2 (TX14(A)) is "an active fragment located within" SEQ ID NO:3. Applicant submits that SEQ ID NO:2 is a modified sequence comprising D-Ala that is not disclosed or claimed in the '080 patent and thus the Applicant's claimed invention is not anticipated by the '080 patent. Accordingly, Applicant respectfully requests withdrawal of this rejection.

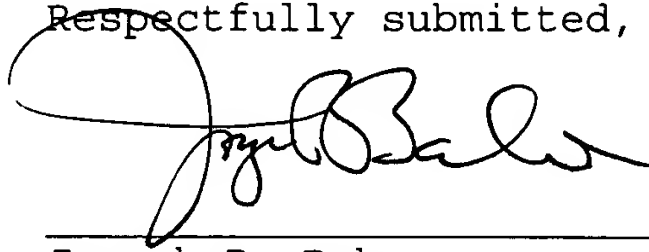
**V. REJECTION UNDER 35 U.S.C. §102(f)**

Claims 3-8 stand rejected under 35 U.S.C. 102(f) because the applicant allegedly did not invent the claimed subject matter as the inventorship is different on U.S. Patent No. 5,696,080. Applicant respectfully traverses this rejection.

Applicant submits that the inventorship is correct in the present application. This is clearly evidenced by the differing subject matter between the '080 patent and the present application, namely SEQ ID NO:2.

No fee is believed to be due with respect to entry of these amendments and remarks. Accompanying this paper is a Request for Continued Examination. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,



Joseph R. Baker  
Reg. No. 40,900

Date: 12/18/03

Fish & Richardson P.C.  
PTO Customer Number: 20985  
12390 El Camino Real  
San Diego, CA 92130  
Telephone: (858) 678-5070  
Facsimile: (858) 678-5099

10353594.doc